MEASURE Human Lyo L-1
for MESURE Reagent

Lot. 116AEL (White Cap)

2℃～8℃ EXP. 2027.06.

Component	Analytical value		1SD	Acceptable range			Method/Instrument	Traceability
Albumin	**41.1**	**g/L**	**1.37**	**37.0**	-	**45.2**	**BCG / Hitachi-7180**	JCCRM613
	4.11	g/dL	0.137	3.70	-	4.52	±3SD range by MEASURE Reagent	(ERM DA470)
ALT	**44.4**	**U/L**	**1.48**	**40.0**	-	**48.8**	**JSCC at 37°C (IFCC w/o PalP) / Hitachi-7180**	JCCRM001d
	0.74	µkat/L	0.025	0.67	-	0.82	±3SD range by MEASURE Reagent	
ALP IFCC	**95.2**	**U/L**	**4.8**	**80.9**	-	**109**	**IFCC at 37°C / Hitachi-7180**	JCCRM001d (IFCC)
	1.59	µkat/L	0.079	1.35	-	1.83	±3SD range by MEASURE Reagent	
Amylase, total	**102**	**U/L**	**5.10**	**86.7**	-	**117**	**IFCC at 37°C / Hitachi-7180**	JCCRM001d
	1.70	µkat/L	0.085	1.45	-	1.96	±3SD range by MEASURE Reagent	
AST	**42.0**	**U/L**	**1.40**	**37.8**	-	**46.2**	**JSCC at 37°C (IFCC w/o PalP) / Hitachi-7180**	JCCRM001d
	0.70	µkat/L	0.023	0.63	-	0.77	±3SD range by MEASURE Reagent	
Bile Acid	**18.1**	**µmol/L**	**1.81**	**12.7**	-	**23.5**	**Enzymatic (3-α-HDS) / Hitachi-7180**	Gravimetry
	7.03	mg/L	0.703	4.92	-	9.14	±3SD range by MEASURE Reagent	
Bilirubin, direct	**9.06**	**µmol/L**	**0.755**	**6.80**	-	**11.3**	**Enzymatic / Hitachi-7180**	NIST
	0.53	mg/dL	0.044	0.40	-	0.66	±3SD range by MEASURE Reagent	
Bilirubin, total	**16.8**	**µmol/L**	**0.56**	**15.1**	-	**18.4**	**Enzymatic / Hitachi-7180**	NIST
	0.98	mg/dL	0.033	0.88	-	1.08	±3SD range by MEASURE Reagent	
Cholesterol, total	**4.09**	**mmol/L**	**0.136**	**3.68**	-	**4.50**	**CHOD-PAP / Hitachi-7180**	JCCRM223
	158	mg/dL	5.3	142	-	174	±3SD range by MEASURE Reagent	(SRM1951a)
HDL Cholesterol	**1.44**	**mmol/L**	**0.096**	**1.15**	-	**1.73**	**Direct enzymatic colorimetry / Hitachi-7180**	JCCRM223
	55.6	mg/dL	3.71	44.5	-	66.7	±3SD range by MEASURE Reagent	(SRM1951a)
LDL Cholesterol	**2.48**	**mmol/L**	**0.124**	**2.11**	-	**2.86**	**Direct enzymatic colorimetry / Hitachi7180**	JCCRM223
	95.9	mg/dL	4.80	81.5	-	110	±3SD range by MEASURE Reagent	(SRM1951a)
CK	**97.9**	**U/L**	**4.90**	**83.2**	-	**113**	**JSCC at 37°C / Hitachi-7180**	JCCRM001d
	1.63	µkat/L	0.082	1.39	-	1.88	±3SD range by MEASURE Reagent	
CK-MB	**27.3**	**U/L**	**3.64**	**16.4**	-	**38.2**	**Immunological UV / Hitachi-7180**	Internal SOP
	0.46	µkat/L	0.061	0.27	-	0.64	±3SD range by MEASURE Reagent	
Creatinine	**81.3**	**µmol/L**	**4.07**	**69.1**	-	**93.5**	**Enzymatic / Hitachi-7180**	JCCRM521
	0.92	mg/dL	0.046	0.78	-	1.06	±3SD range by MEASURE Reagent	(ID-MS)
GGT	**37.6**	**U/L**	**1.50**	**33.1**	-	**42.1**	**JSCC at 37°C / Hitachi-7180**	JCCRM001d
	0.63	µkat/L	0.025	0.55	-	0.70	±3SD range by MEASURE Reagent	
Glucose	**4.28**	**mmol/L**	**0.143**	**3.85**	-	4.71	**HK/G6P-DH / Hitachi-7180** **HDAOS-POD / Hitachi-7180**	JCCRM521
	77.1	mg/dL	2.57	69.4	-	84.8	±3SD range by MEASURE Reagent	(ID-MS/SRM917)
LDH IFCC	**150**	**U/L**	**5.0**	**135**	-	**165**	**IFCC at 37°C / Hitachi-7180**	JCCRM001d
	2.51	µkat/L	0.084	2.25	-	2.76	±3SD range by MEASURE Reagent	
Protein,total	**64.2**	**g/L**	**2.14**	**57.8**	-	**70.6**	**Modified Biuret / Hitachi-7180**	JCCRM613
	6.42	g/dL	0.214	5.78	-	7.06	±3SD range by MEASURE Reagent	(srm927)
Trglyceride	**0.77**	**mmol/L**	**0.026**	**0.69**	-	**0.84**	**GPO/PAP**	JCCRM223
	67.2	mg/dL	2.24	60.5	-	73.9	±3SD range by MEASURE Reagent	(ID-MS)
(TG-T)	**1.10**	**mmol/L**	**0.037**	**0.99**	-	**1.22**	**GPO/PAP**	JCCRM223
	96.9	mg/dL	3.23	87.2	-	107	±3SD range by MEASURE Reagent	(ID-MS)
Urea Nitrogen	**4.76**	**mmol/L**	**0.159**	**4.29**	-	**5.24**	**Urease-UV / Hitachi-7180**	JCCRM521
	13.3	mg/dL	0.44	12.0	-	14.6	±3SD range by MEASURE Reagent	(id-ms/srm912)
Uric acid	**292**	**µmol/L**	**9.7**	**263**	-	**321**	**Uricase-POD / Hitachi-7180**	JCCRM521
	4.91	mg/dL	0.164	4.42	-	5.40	±3SD range by MEASURE Reagent	(ID-MS)

Acceptable range : ± 3SD

LDH, ALP : As the method has already been switched to IFCC, it has been removed from this lot.

Glucose : Added values using the HK/G6P-DH method

UMA Co,.Ltd.

Tester	Quality Control Manager	Manufacturing Control Manager
吉海	吉海	横瀬

MEASURE Human Lyo L-1

(Other Method)

Lot. 116AEL

(White Cap)

2°C～ 8°C EXP. 2027.06.

Component	Analytical value		U *	Acceptable range	Method/Instrument	Traceability
ALT	**45.0**	**U/L**	**4**	**41.0 - 49.0**	IFCC 37°C with PalP	IFCC
	0.75	µkat/L	0.07	0.68 - 0.82		
Albumin	**41.4**	**g/L**	**3.8**	**37.6 - 45.2**	BCG	CRM470
	4.14	g/dL	0.38	3.76 - 4.52		
ALP	**99.0**	**U/L**	**10**	**89.0 - 109**	IFCC at 37°C	IFCC
	1.65	µkat/L	0.17	1.49 - 1.82		
Amylase, total	**99.0**	**U/L**	**7**	**92.0 - 106**	IFCC at 37°C	IFCC
	1.65	µkat/L	0.12	1.54 - 1.77		
Amylase, pancreas	**49.0**	**U/L**	**3**	**46.0 - 52.0**	Enzymatic colorimetry 37°C	
	0.82	µkat/L	0.05	0.77 - 0.87		
AST	**44.0**	**U/L**	**4**	**40.0 - 48.0**	IFCC 37°C with PalP	IFCC
	0.73	µkat/L	0.07	0.67 - 0.80		
Bilirubin, direct	**4.70**	**µmol/L**	**0.7**	**4.00 - 5.40**	Diazo	
	0.27	mg/dL	0.04	0.23 - 0.32		
Bilirubin, total	**13.7**	**µmol/L**	**2.0**	**11.7 - 15.7**	DPD	Doumas method
	0.80	mg/dL	0.12	0.68 - 0.92		
Calucium	**2.17**	**mmol/L**	**0.15**	**2.02 - 2.32**	NM-BAPTA	SRM909b
	8.70	mg/dL	0.60	8.10 - 9.30		
Chloride	**106**	**mmol/L**	**5**	**101 - 111**	Indirect ISE	Gravimetry
Cholesterol, total	**3.95**	**mmol/L**	**0.24**	**3.71 - 4.19**	CHOD/PAP	ID-MS
	153	mg/dL	9	143 - 162		
HDL Cholesterol	**1.17**	**mmol/L**	**0.22**	**0.95 - 1.39**	Direct enzymatic colorimetry	SRM1951a
	45.2	mg/dL	9	36.7 - 53.8		
LDL Cholesterol	**2.30**	**mmol/L**	**0.20**	**2.10 - 2.50**	Direct enzymatic colorimetry	SRM1951a
	88.9	mg/dL	8	81.2 - 96.7		
CK	**104**	**U/L**	**8**	**96.0 - 112**	IFCC at 37°C	IFCC
	1.74	µkat/L	0.13	1.60 - 1.87		
CK-MB	**20.0**	**U/L**	**5**	**15.0 - 25.0**	Immunological UV	ERM-AD455/IFCC
	0.33	µkat/L	0.08	0.25 - 0.42		
Copper	**16.1**	**µmol/L**	**1.2**	**14.9 - 17.3**	ICP-MS	SRM 3114
	102	µg/dL	8	95 - 110		
Creatinine	**75.5**	**µmol/L**	**6**	**69.5 - 81.5**	Enzymatic colorimetry	ID-MS
	0.85	mg/dL	0.07	0.79 - 0.92		
Digoxin	**0.994**	**nmol/L**			LIA Access	
GGT	**36.0**	**U/L**	**3**	**33.0 - 39.0**	IFCC at 37°C	IFCC
	0.60	µkat/L	0.05	0.55 - 0.65		
GLDH	**5.20**	**U/L**	**0.4**	**4.80 - 5.60**	DGKC 37°C	
	0.09	µkat/L	0.01	0.08 - 0.09		
Glucose	**4.38**	**mmol/L**	**0.36**	**4.02 - 4.74**	HK/G6P-DH	ID-MS
	78.9	mg/dL	6	72.4 - 85.4		
Iron	**17.9**	**µmol/L**	**1.4**	**16.5 - 19.3**	Ascorbate/FerroZine	SRM937
	99.9	µg/dL	7.8	92.1 - 108		
Lactate	**1.99**	**mmol/L**	**0.2**	**1.79 - 2.19**	LOD/POD	Primery reference material
	17.9	mg/dL	1.8	16.1 - 19.7		
LDH	**144**	**U/L**	**14**	**130 - 158**	IFCC at 37°C	IFCC
	2.40	µkat/L	0.23	2.17 - 2.64		
Lipase	**47.0**	**U/L**	**5**	**42.0 - 52.0**	Enzymatic colorimetry 37°C	Roche reagent manual measurement
	0.78	µkat/L	0.08	0.70 - 0.87		
Lithium	**0.795**	**mmol/L**	**0.02**	**0.78 - 0.82**	Colorimetry	
	0.55	mg/dL	0.01	0.54 - 0.57		
Magnesium	**0.85**	**mmol/L**	**0.03**	**0.82 - 0.88**	Xylidyl-blue	Gravimetry
	2.07	mg/dL	0.07	1.99 - 2.14		
Phosphorus	**1.01**	**mmol/L**	**0.06**	**0.95 - 1.07**	Ammonium phosphomoplybdate	Primary reference material
	3.13	mg/dL	0.19	2.94 - 3.31		
Potassium	**3.95**	**mmol/L**	**0.15**	**3.80 - 4.10**	Indirect ISE	Gravimetry
Protein total	**62.0**	**g/L**	**5.1**	**56.9 - 67.1**	Biuret	SRM927c
	6.20	g/dL	0.51	5.69 - 6.71		
Sodium	**139**	**mmol/L**	**5**	**134 - 144**	Indirect ISE	Gravimetry
Theophyline	**71.8**	**µmol/L**			KIMS	Gravimetry
Total Bile Acid	**25.6**	**µmol/L**	**4**	**21.6 - 29.6**	Enzymatic endpoint	
	9.98	mg/L	1.56	8.42 - 11.5		

MEASURE Human Lyo L-1

(Other Method)

Lot. 116AEL

(White Cap)

2°C～ 8°C EXP. 2027.06.

Component	Analytical value		U *	Acceptable range			Method/Instrument	Traceability
Trglyceride	**1.12**	**mmol/L**	**0.08**	**1.04**	-	**1.20**	GPO/PAP	ID-MS
	99.2	mg/dL	7	92.1	-	106		
UIBC	**39.1**	**μmol/L**	**5.5**	**33.6**	-	**44.6**	FeroZine®	Primary reference material
	218	μg/dL	31	188	-	249		
Urea	**4.46**	**mmol/L**	**0.4**	**4.06**	-	**4.86**	Urease/GLZDH	SRM909b
	12.5	mg/dL	1.1	11.4	-	13.6		
Uric acid	**289**	**μmol/L**	**19**	**270**	-	**308**	Uricase/POD	ID-MS
	4.86	mg/dL	0.32	4.54	-	5.18		
Zinc	**27.9**	**μmol/L**	**2.6**	**25.3**	-	**30.5**	ICP-MS	SRM 3168a
	182	μg/dL	17	165	-	199		

* (u) : uncertainty Acceptable range : ± 3SD

The following component will be removed from this lot and later, because the manufacturer's assigned values are not available.

Apo-A, Apo-B CHE, Estoradiol, Ferritin, Folate, HBDH, β-HCG, Homocystaine, IgA, IgG, IgM, NEFA, Osmolality, Phospholipids, Progesterone, f-T3,T3,f-T4,T4,Testosteron, Transferrin, TSH.